



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/567,078

04/07/2006

Jan Bastiaan Bouwstra

0807620.00112

2404

545 7590 10/09/2009

IP Patent Docketing
K&L GATES LLP
599 Lexington Avenue
33rd Floor
New York, NY 10022-6030

EXAMINER

KIM, YUNSOO

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

10/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,078	Applicant(s) BOUWSTRA ET AL.	
	Examiner YUNSOO KIM	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-25 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 16 and 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/31/09 has been entered.

2. Claims 1-13 and 15-25 are pending.

Applicants' request for rejoinder is acknowledged. Applicant has asserted that the rejoinder of product claims upon allowance of process claim is also proper.

However, the current status of the rejoinder practice allows to rejoin the withdrawn process claims upon allowance of the elected product claims. It is noted that Applicants have elected the process claims and the product claims have withdrawn. MPEP 821.04.

Given that the patentability of a product does not depend on its method of production, the rejoinder of product claims upon allowance of method claims is not proper pursuant to MPEP 821.04. See also MPEP 2113.

Claims 11, 12, 15 and 17 stand withdrawn from further consideration by the examiner 37CFR 1.142(b) as being drawn to a nonelected invention.

Claims 1-10, 13, 16 and 18-25, drawn to a method for the preparation of a vaccine composition are under consideration in the instant application.

3. In light of Applicants' response filed on 7/31/09, the objection and the rejections set forth in the office action mailed on 2/13/09 have been withdrawn.

Art Unit: 1644

4. The following new ground of rejection is set forth herein.
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-10, 13, 16 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 01/34801 (IDS reference, of record) in view of Greiff et al. (Applied Microbiology, 1970, vol. 20, p. 935-938).

The '801 publication teaches a method of producing a vaccine formulation comprising an antigen and a recombinant gelatin (p. 86, claims 39, 1, 18-19) and the vaccine formulation is lyophilized (p. 66-67). The '801 publication further teaches that the molecular weight of gelatin includes 10 to 30kDa and about 8kDa or 9KDa (p. 8, lines 10-15).

Art Unit: 1644

Note that the referenced vaccine composition comprising a gelatin and antigen is dry and powder (claims 18-19) after lyophilization. Moreover, the '801 publication teaches that the recombinant gelatin is homogenous (p. 40), claim 2 reciting "homodisperse", which means at least 90% of gelatin has molecular weight lies within +/- 10% around the selected molecular weight (specification 10), and claim 5 and 20 reciting "optimally aligned by GAP" are included in this rejection (p.17-18, overlapping paragraph).

Given that gelatin cannot be reconstituted if lyophilized as gel and the referenced vaccine is reconstituted, claim 25 reciting "lyophilized gelatin in the sol state" is included in this rejection.

The disclosure of the '801 publication differs from the claimed invention in that it does not teach reducing and maintaining water content to be below 2 weight percent as is recited in claims 1 and 16 of the instant application.

Greiff teaches that the lyophilization of influenza virus and the moisture content of 1.6% after lyophilization found best for stabilization of vaccine composition without affecting the efficacy of the vaccine (abstract, Table 3, discussion). Greiff further teaches that the time of lyophilization is related to percent residual moisture (e.g. 28 hrs for 1.5% residual moisture, 48 hrs for 0.6 % residual moisture and 20 hrs for 3% residual moisture, respectively, p. 935, 2nd col.).

Claim 8 is included in this rejection because having "the water content below 2% " expects to prevent crystallization of the recombinant gelatin for at least 7 years upon lyophilization of vaccine to the water content to 1.6%. Further, claims 9-10 and 21-22 are included in this rejection because preparations are packaged in special vials under vacuum and under gas (p.935).

Art Unit: 1644

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to reduce water content to 1.6% (e.g. below 2%) as taught by Greiff in the method of making vaccine comprising gelatin as taught by the '801 publication.

One of ordinary skill in the art would have been motivated to do so because the reducing water content to 1.6% increased the stability of vaccine composition of the order of years as compared to the other test compositions and the dryness of the composition is time dependent and be monitored.

From the teachings of references, it would have been obvious to one of ordinary skill in the art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time of invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

7. No claims are allowable.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to YUNSOO KIM whose telephone number is (571)272-3176. The examiner can normally be reached on M-F,9-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
October 2, 2009

/Michael Szperka/
Primary Examiner, Art Unit 1644